Applicants: Francis G. Fang and Shiping Xie

Serial No.: 09/903,101 Filed : July 11, 2001

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Remarks

Claims 2 and 4 were pending in the subject application. Applicants have by this Amendment, added new claim 5 and amended claims 2 and 4. Thus, amended claims 2 and 4 and new claim 5 are currently pending in the subject application.

Support for new claim 5 can be found *inter alia* in the specification, as originally filed, on page 10, first paragraph, and page 3, line 2 to end of page 5.

Restriction/Election

On page 2 of the September 5, 2002 Office Action, the Examiner alleged that applicants' Response to May 8, 2002 Restriction Requirement is not fully responsive. The Examiner stated that the May 8, 2002 Communication, a copy of which is attached hereto as **Exhibit A**, was an election requirement, while applicants' response treated the May 8, 2002 Communication as a Restriction Requirement consisting of three groups. The Examiner also alleged that the restriction consisting of three groups was not set forth by the Examiner. The Examiner further requested election of a species exemplified in the specification in response to this Communication.

In response, applicants admit to some confusion. The May 8, 2002 Communication specifically stated in the fourth line of page 2 that "a modification to the restriction" was being made and proceeded to list three (3) groups as opposed to there being only two (2) groups in the September 25, 2001 Restriction Requirement it was presumably modifying. Within each of the three groups, the May 8, 2002 Communication also required an election of species. On page 3, line 8, the May 2002 Communication cited 37 C.F.R. §1.143 in support of the "requirement." 37 C.F.R. §1.143

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clearly refers to a "requirement for restriction." Finally, also on page 3, lines 9-10 of the May 8, 2002 Communication, the Examiner referred to a "non-elected invention," which term is properly used in a restriction, not an election of species context. Based on their understanding that the May 8, 2002 Communication was a restriction requirement, applicants filed their June 7, 2002 response.

In response to the election of species request, applicants elect the compound of Example 3 on pages 15 - 16 of the specification for the purposes of initiating examination. Applicants point out that the compound of Example 3 is being claimed only as part of a generic claim 2.

However, applicants respectfully request a shift from the invention of claim 2 to the invention of new claim 5 pursuant to M.P.E.P. §819.01. A shift may be permitted "where the shift results in no additional work or expense, and particularly where the shift reduces work by simplifying the issues." M.P.E.P. §819.01. In the instant situation, the requested shift clearly results in no additional work or expense because a search has not yet been performed.

Moreover, applicants point out that their election of claim 2 has not yet become fixed. According to M.P.E.P. §818.01, an election becomes fixed only when "the claims in an application have received an action on their merits." Because an action on the merits has not been issued, applicants' election has not yet been "fixed" and this requested shift should be granted.

Yet furthermore, 37 C.F.R. §1.115 explicitly authorizes the entry of a preliminary amendment filed before the first action on the merits. A first action on the merits has not been issued as of

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this request. Thus, if the shift requested herein is not granted, applicants alternatively request that this communication be considered to be a preliminary amendment pursuant to 37 C.F.R. §1.115 requesting cancellation of claims 2 and 4, and examination of new claim 5.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of this Amendment and Response to Restriction Requirement. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

Assistant Commissioner for Patents Washington, DC 20231.

Reg. No. 28,678 Gary J. Gershik Reg. No. 39,992

John P. White

Registration No. 28,678

Gary J. Gershik

Registration No. 39,992

Attorneys for Applicants

Cooper & Dunham LLP

1185 Avenue of the Americas New York, New York 10036

(212) 278-0400

Marked-Up Claim

2. (Twice amended) A compound of Formula (II):

$$R_3$$
 R_4
 R_6
 R_6
 R_8
 R_8
 R_8
 R_8
 R_8
 R_8

wherein:

wherein:

 R_1 is selected from hydrogen, lower alkyl, (C_{3-7}) eyeloalkyl, (C_{3-7}) eyeloalkyl lower alkyl, lower alkyl, or alkoxy alkyl;

 (C_1-C_3) (C_1-C_3) (C_1-C_3) (C_1-C_3) (C_1-C_3) (C_1-C_3) (C_1-C_3) (C_1-C_3) is selected from hydrogen, lower alkyl, (C_{3-7}) cycloalkyl, (C_{3-7}) cycloalkyl lower alkyl, lower alkenyl, hydroxy lower alkyl, or alkoxy alkyl, or $(-CH_2NR_7R_8)$, wherein: (C_1-C_4)

i) R_7 and R_8 , which may be the same or different, are independently selected (C_1-C_2) from hydrogen, lower alkyl, (C_{3-7}) cycloalkyl, (C_{3-7}) cycloalkyl lower alkyl, lower alkenyl, hydroxy lower alkyl, or lower alkoxy lower alkyl; or (C_1-C_2)

ii) R_7 represents hydrogen, lower alkyl, (C_{3-7}) cycloalkyl, (C_{3-7}) cycloalkyl lower alkyl, lower alkenyl, hydroxy lower alkyl, or lower alkoxy lower alkyl, and R_8 represents $-COR_9$,

 (C_{3-7}) (C_{3-7}) (C_{3-7}) (C_{3-7}) (C_{3-7}) cycloalkyl, perhalo-lower alkyl, (C_{3-7}) cycloalkyl lower alkyl, lower alkenyl, hydroxy lower alkyl, lower alkoxy, lower alkoxy lower alkyl; or (C_{3-7})

(6,-(2)

iii) R_7 represents hydrogen or lower-alkyl; and R_8 represents diphenyl-methyl or – $(CH_2)_1$ Ar

wherein:

t is 0 to 5 and Ar represents phenyl, furyl, pyridyl, N-methylpyrrolyl, imidazolyl optionally substituted with one or more substituents selected from hydroxy, methyl, halogen, and amino; or

iv) R_7 and R_8 taken together with the linking nitrogen form a saturated 3 to 7 atom heterocyclic group of formula (IA)



wherein:

Y represents O, S, SO, SO₂, CH₂ or NR₁₀,

wherein:

R₁₀ represents hydrogen, lower alkyl, perhalo lower alkyl, aryl, aryl

substituted with one or more substituents selected from lower (C_1-C_2) alkyl, lower alkoxy, halogen, nitro, amino, lower alkyl amino, (C_1-C_2) perhalo-lower alkyl, hydroxy lower alkyl, lower alkoxy lower alkyl groups or $-COR_{11}$,

wherein:

((,-(3)) (()

 R_{11} represents hydrogen, lower alkyl, perhalo-lower alkyl, lower alkoxy, aryl, aryl substituted with one ((,-(g)) or more substituents selected from lower alkyl, ((,-(g)) perhalo-lower alkyl, hydroxy lower alkyl, lower ((,-(g)) alkoxy lower alkyl-groups;

(6,-(9)

 R_3 and R_4 are independently selected from hydrogen, lower alkyl, (C_{3-7}) cycloalkyl, (C_{3-7})

R₃ and R₄ taken together form a saturated 5 to 6 atom heterocyclic group of formula (IB)

wherein,

n represents the integer 1 or 2; or

R₃ represents –OCONR₁₂R₁₃,

wherein,

 R_{12} and R_{13} , which may be the same or different, are independently selected from hydrogen, a substituted or unsubstituted alkyl group with 1-4 carbon atoms or a substituted or unsubstituted carbocyclic or heterocyclic group, with the proviso that when both or R_{12} and R_{13} are substituted or unsubstituted alkyl groups, they may be combined together with the nitrogen atom, to which they are bonded, to form a heterocyclic ring which may be interrupted with $-O_-$, $-S_-$ and/or $-N_-R_{14}$ in which R_{14} is hydrogen, a substituted or unsubstituted alkyl group with 1-4 carbon atoms or a substituted or unsubstituted phenyl group;

R₅ represents hydrogen or alkyl; and R₆ represents hydrogen or alkyl,

or a pharmaceutically acceptable salt thereof.

4. (Amended) A compound of formula (IV):

$$R_3$$
 R_4
 R_5
 R_1
 R_1
 R_2
 R_1
 R_2
 R_3
 R_4
 R_5
 R_5
 R_5
 R_5

wherein:

X represents triflate or halo;

 R_1 and R_2 , which may be the same or different, are independently selected from hydrogen, (C_1 - C_2)

| (C_1 - C_2)
| (C_1 - C_2)
| (C_3 - C_3)

- i) R_7 and R_8 , which may be the same or different, are independently selected (C_1-C_8) from hydrogen, lower alkyl, (C_{3-7}) cycloalkyl, (C_{3-7}) cycloalkyl lower alkyl, lower (C_1-C_8) alkenyl, hydroxy lower alkyl, or lower alkoxy lower alkyl; or
- ii) R_7 represents hydrogen, lower alkyl, (C_{3-7}) cycloalkyl, (C_{3-7}) cycloalkyl lower alkyl, lower alkenyl, hydroxy lower alkyl, or lower alkoxy lower alkyl, and R_8 represents $-COR_9$, wherein:

((,-(z))

R₉ represents hydrogen, lower alkyl, perhalo-lower alkyl, (C₃₋₇)cycloalkyl,

(C₃₋₇) cycloalkyl lower alkyl, lower alkenyl, hydroxy lower alkyl, lower

((,-(z))

alkoxy, lower alkoxy lower alkyl; or

(4-(2)

iii) R_7 represents hydrogen or lower alkyl; and R_8 represents diphenyl-methyl or – (CH_2) , Ar

wherein:

t is 0 to 5 and Ar represents phenyl, furyl, pyridyl, N-methylpyrrolyl, imidazolyl optionally substituted with one or more substituents selected from hydroxy, methyl, halogen, and amino; or

iv) R₇ and R₈ taken together with the linking nitrogen form a saturated 3 to 7 atom heterocyclic group of formula (IA)



wherein:

Y represents O, S, SO, SO₂, CH₂ or NR₁₀,

wherein:

R₁₀ represents hydrogen, lower-alkyl, perhalo lower alkyl, aryl, aryl substituted with one or more substituents selected from lower ((1,-(3))) alkyl, lower alkoxy, halogen, nitro, amino, lower alkyl amino, ((1,-(3))) perhalo-lower alkyl, hydroxy lower alkyl, lower alkoxy lower-alkyl groups or - COR₁₁,

wherein:

R₁₁ represents hydrogen, lower alkyl, perhalo-lower alkyl, lower alkoxy, aryl, aryl substituted with one ((1-(1))) or more substituents selected from lower alkyl, ((1-(1))) perhalo-lower alkyl, hydroxy lower alkyl, lower ((1-(1))) alkoxy lower alkyl groups;

 R_3 represents $-OCONR_{12}R_{13}$,

wherein,

R₁₂ and R₁₃, which may be the same or different, are independently selected from hydrogen, a substituted or unsubstituted alkyl group with 1-4 carbon atoms or a substituted or unsubstituted carbocyclic or heterocyclic group, with the proviso that when both or R₁₂ and R₁₃ are substituted or unsubstituted alkyl groups, they may be combined together with the nitrogen atom; to which they are bonded; to form a heterocyclic ring which may be interrupted with -O-, -S- and/or -N-R₁₄ in which R₁₄ is hydrogen, a substituted or unsubstituted alkyl group with 1-4 carbon atoms or a substituted or unsubstituted phenyl group;

R₅ represents hydrogen or alkyl; and
 R₆ represents hydrogen or alkyl,
 or a pharmaceutically acceptable salt thereof.

5. (New) A compound of Formula (V):

$$R_3$$
 R_4
 N
 X
 (V)

wherein:

 R_1 and R_2 is selected from hydrogen, (C_1-C_8) alkyl, (C_{3-7}) cycloalkyl, (C_{3-7}) cycloalkyl (C_1-C_8) alkyl, lower alkenyl, hydroxy (C_1-C_8) alkyl, or alkoxy alkyl, or $(-CH_2NR_7R_8)$, wherein:

i) R_7 and R_8 , which may be the same or different, are independently selected from hydrogen, (C_1-C_8) alkyl, (C_{3-7}) cycloalkyl, (C_{3-7}) cycloalkyl, (C_1-C_8) alkyl, lower alkenyl, hydroxy (C_1-C_8) alkyl, or lower alkoxy (C_1-C_8) alkyl; or

ii) R_7 represents hydrogen, (C_1-C_8) alkyl, $(C_{3.7})$ cycloalkyl, $(C_{3.7})$ cycloalkyl (C_{1-C_8}) alkyl, lower alkenyl, hydroxy (C_1-C_8) alkyl, or lower alkoxy (C_1-C_8) alkyl, and R_8 represents $-COR_9$.

wherein:

 R_9 represents hydrogen, (C_1-C_8) alkyl, perhalo- (C_1-C_8) alkyl, (C_{3-7}) cycloalkyl, (C_{3-7}) cycloalkyl (C_1-C_8) alkyl, lower alkenyl, hydroxy (C_1-C_8) alkyl, lower alkoxy, lower alkoxy (C_1-C_8) alkyl; or

iii) R_7 represents hydrogen or (C_1-C_8) alkyl; and R_8 represents diphenyl-methyl or $-(CH_2)_{t}$ Ar

wherein:

t is 0 to 5 and Ar represents phenyl, furyl, pyridyl, N-methylpyrrolyl, imidazolyl optionally substituted with one or more substituents selected

from hydroxy, methyl, halogen, and amino; or

iv) R₇ and R₈ taken together with the linking nitrogen form a saturated 3 to 7 atom heterocyclic group of formula (IA)



wherein:

Y represents O, S, SO, SO₂, CH₂ or NR₁₀, wherein:

 R_{10} represents hydrogen, (C_1-C_8) alkyl, perhalo (C_1-C_8) alkyl, aryl, aryl substituted with one or more substituents selected from (C_1-C_8) alkyl, lower alkoxy, halogen, nitro, amino, (C_1-C_8) alkyl amino, perhalo- (C_1-C_8) alkyl, hydroxy (C_1-C_8) alkyl, lower alkoxy (C_1-C_8) alkyl groups or $-COR_{114}$

wherein:

 R_{11} represents hydrogen, (C_1-C_8) alkyl, perhalo- (C_1-C_8) alkyl, lower alkoxy, aryl, aryl substituted with one or more substituents selected from (C_1-C_8) alkyl, perhalo- (C_1-C_8) alkyl, hydroxy (C_1-C_8) alkyl, lower alkoxy (C_1-C_8) alkyl groups;

 R_3 and R_4 are independently selected from hydrogen, (C_1-C_8) alkyl, (C_{3-7}) cycloalkyl, (C_{3-7}) cycloalkyl (C_1-C_8) alkyl, lower alkenyl, hydroxy (C_1-C_8) alkyl, or alkoxy alkyl; or

R₃ and R₄ taken together form a saturated 5 to 6 atom heterocyclic group of formula (IB)

 $\underline{\hspace{1cm}}$ (IB)

wherein,

n represents the integer 1 or 2; or

R₃ represents -OCONR₁₂R₁₃,

wherein,

 R_{12} and R_{13} , which may be the same or different, are independently selected from hydrogen, a substituted or unsubstituted alkyl group with 1-4 carbon atoms or a substituted or unsubstituted carbocyclic or heterocyclic group, or R_{12} and R_{13} together with the nitrogen atom to which they are bonded form a heterocyclic ring which may be interrupted with $-O_{-}$, $-S_{-}$ and/or $-N_{-}R_{14}$ in which R_{14} is hydrogen, a substituted or unsubstituted alkyl group with 1-4 carbon atoms or a substituted or unsubstituted phenyl group;

R₅ represents hydrogen or alkyl; and
R₆ represents hydrogen or alkyl,
or a pharmaceutically acceptable salt thereof;

X represents triflate, chloro-, bromo-, or iodo-; and

Z represents chloro-, bromo-, iodo- or OR₁₅;

wherein R₁₅ represents hydrogen, triflate, mesylate or tosylate.



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APPLICATION NO.	Fli	LING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/903,101	0	7/11/2001	Francis Gerard Fang	GI2129.US2D	2707
;	7590	05/08/2002			
Mark L. Bosse			EXAMINER		

Mark L. Bosse Gilead Sciences, Inc. 333 Lakeside Drive Foster City, CA 94404 EXAMINER WRIGHT, SONYA N

ART UNIT PAPER NUMBER

1626

DATE MAILED: 05/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

•		Application No.	Applicant(s)					
	Office Action Summary	09/903,101	FANG ET AL.					
Applicants	received this action on May 3,	Examiner	Art Unit					
		Sonya Wright	1626					
Period for Re	e MAILING DATE of this communication appo	ears on the cover sheet with the c	orrespondence address					
- Extensions after SIX (6 - If the perioc - If NO periox - Faiture to re - Any repty re	ENED STATUTORY PERIOD FOR REPLY LING DATE OF THIS COMMUNICATION. of time may be available under the provisions of 37 CFR 1.13 MONTHS from the mailing date of this communication. If for reply specified above is less than thirty (30) days, a reply of for reply is specified above, the maximum statutory period with the set or extended period for reply will, by statute, see you will be office tater than three months after the mailing tent term adjustment. See 37 CFR 1.704(b).	6(a). In no event, however, may a reply be tim within the statutory minimum of thirty (30) days ill apply and will expire SIX (6) MONTHS from	nely filed s will be considered timely.					
earned pate Status	ent term adjustment. See 37 CFR 1.704(b).	uate of this communication, even if timely filed	, may reduce any					
	sponsive to communication(s) filed on							
· 		— · s action is non-final.	AY 17 2002					
3) <u></u> Sin	ice this application is in condition for allower	non overall factor of the second	:					
clos Disposition o	sed in accordance with the practice under E	x parte Quayle, 1935 C.D. 11, 4	osecution as to the merits is 53 O.G. 213.					
	m(s) $1-3$ is/are pending in the application.	10	n. 6.8.02					
	Of the above claim(s) is/are withdraw		n.7.8.02					
5) Clair	m(s) is/are allowed.		n. 8. 8. 02					
	m(s) is/are rejected.		-					
7)☐ Clair	m(s) is/are objected to.		1.9.8.02					
8)⊠ Clain	n(s) <u>1-3</u> are subject to restriction and/or ele	ction requirement. $5{ m m}$	1.10.8.02					
Application Pa	apers	6m	.11.8.02 A?					
9) The s	pecification is objected to by the Examiner.							
10)∐ The d	rawing(s) filed on is/are: a)□ accepto	ed or b) objected to by the Exan	niner.					
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is: a) approved b) disapproved by the Examiner								
The o	proved, corrected drawings are required in reply	to this Office action.						
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 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 								
3.	Copies of the codified against at the	have been received in Application	on No					
	Copies of the certified copies of the priority application from the International Bures attached detailed Office action for a list of							
14)☐ Acknow	vledgment is made of a claim for domestic	Priority under 35 U.S.C. & 119/6)	l. Maa novisianal aasta u					
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Attachment(s)		120	ana/01727.					
2) Notice of Draft 3) Information Di	erences Cited (PTO-892) fisperson's Patent Drawing Review (PTO-948) isclosure Statement(s) (PTO-1449) Paper No(s)		PTO-413) Paper No(s) stent Application (PTO-152)					
J.S. Patent and Trademark OPTO-326 (Rev. 04-01)	Office Action	n Summary						

Application/Control Number: 09/903,101

Art Unit: 1626

DETAILED ACTION

Claims 1-3 are pending in this application.

Applicant's election with traverse of Group I in Paper No. 5 filed 3-16-02 is acknowledged.

Based on Applicants traversal, a modification to the restriction was made as following:

Group I, claim 1, drawn to a process of preparing compounds of formula I from formula II. If this group is elected, further election of a single disclosed species to be made by the process is also required.

Group II, claim 3, drawn to compounds. If this group is elected, further election of a single disclosed species is also required.

Group III, claim 2, drawn to compounds which are not encompassed by claim 3. If this group is elected, further election of a single disclosed species is also required.

Should Applicant traverse on the ground that the species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention. Were Applicant to argue that the Groups are not distinct, there could be no patentability of any claim over Comins et al., AN 1993:169399,

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compound IV. Compound IV in Comins et al. is a tautomer of the instant compounds, therefore, it can be used as a 103 reference.

Upon the election of a single disclosed species, a generic concept inclusive of the elected species will be identified by the examiner for examination along with the elected species.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonya Wright, whose telephone number is (703) 308-4539. The examiner can normally be reached on Monday-Friday from 7:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308-4537. The Unofficial fax phone number for this Group is (703) 308-7921. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

Art Unit: 1626

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-1235.

Art Unit: 1626

Celia Chang

Primary Examiner

Group 1600

Sonya Wright

May 3, 2002

	Notice of Reference	- 77.001 1 1	2002 Examiner		Art Unit	
		TE.	Sonya Wright		1626	Page 1 of 1
		TRADEN	PATENT DOCUME	NTS		• • ———————————————————————————————————
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	reference is not being furnished with thi					

Notice of References Cited

Application/Control No.

Applicant(s)/Patent Under Reexamination FANG ET AL.

Part of Paper No. 5